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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,412	10/27/2000	Haskell E. Mullins	56108USA1A.002	5638

32692 7590 03/31/2004

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EXAMINER	
WEISS JR, JOSEPH FRANCIS	

ART UNIT	PAPER NUMBER
3743	14

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/698,412	MULLINS ET AL.	
	Examiner	Art Unit	
	Joseph F Weiss Jr.	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12 & 13*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-8, 12-17, 21-22, 24-27, 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burstroem (FOA Report C40208-C1 (C2) in view of Fennelly ("An Automated Aerosol Generator to Reduce Variability in Qualitative Fit Testing of Respirators" KP Fennelly et al American Journal of Respiratory and Critical Care medicine Vol. 159, Supp #3 pages PA 615 DTD 1999).

Burstroem substantially discloses the instant application's claimed invention to include a qualitative respirator fit testing system comprising a plurality of test stations (note fig 3 & cartoon on cover, specifically the human head height openings to the chamber) that are in fluid communication with each other, but does not explicitly disclose an automated aerosol generator for generating the aerosol to fit test the masks. However, Fennelly discloses such (See abstract's disclosure). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Fennelly and used them with the device of Burstroem. The suggestion/motivation for doing so would have been to insure

optimal test aerosol was delivered to the test station. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 22, the suggested device substantially discloses the instant application's device, but does not disclose the provision of a plurality of aerosol generators, dedication one station to each test station, i.e. the duplication of a known part for a known purpose. However, at the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have duplicated the number of aerosol generators to match the number of test stations. The suggestion/motivation for doing so would have been to process more personnel for mask test fit more quickly. Therefore it would have been obvious to ob duplicated a known part for a known purpose to obtain the instant application's claimed invention.

Furthermore, it is noted that applicant's specification does not set forth this duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the duplication of a known part for a known purpose to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 24, the suggested device discloses an aerosol generator in fluid communication with at least two test stations.

In regards to claim 25, the suggested device discloses the use of a respirator fit test hood for each test station. (Note the test stations and structure of Burstroem serve as a "hood")

In regards to method claims 1-20 & 26-36, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 21-22, 24-25, with specific reference to the various method steps noted as follows:

In regards to claims 1, 15, 16-17, 27 the suggested device discloses receiving test subject(s) feedback from testing, to include feedback regarding "sensitivity" aerosols and when "remote" (Note Burstroem's use of Qualitative Mask Test Fitting QMTF).

In regards to claims 2-3, 7, 34 the suggested device discloses simultaneous testing and prompting of test subjects at the stations. (Note Burstroem's use of Qualitative Mask Test Fitting QMTF, Note Appendix c of DA Pam 40-8 regarding what the industry standard/definition of "Qualitative test fitting is defined, contains inherently implicates)

In regards to claim 6-7, regarding the use of predetermined time intervals, the suggested device discloses such (See Burstroem's notation of number of personnel to

be tested w/in a hour, note disclosure of Fennelly regarding control and operation of aerosol generator)

In regards to claim 8, the suggested device is fully capable of delivering different amounts of aerosol to different test stations/subjects.

In regards to claim 13-14, 32-33 the suggested device discloses the prompting of test subjects to perform activities during testing. (Note Burstroem's use of Qualitative Mask Test Fitting QMTF, Note Appendix c of DA Pam 40-8 regarding what the industry standard/definition of "Qualitative test fitting is defined, contains inherently implicates)

In regards to claim 26, the suggested device is fully capable of remote automated test fitting.

In regards to claims 35 & 36, the suggested device is fully capable of being provided at a remote location in multiples for simultaneous operation.

In regards to claims 37 & 38, the suggested device is fully capable of delivering repeatable selected amounts of test aerosol to a test station or delivering different selected amounts of test aerosol to at least two different test stations using an automated aerosol generator.

1. Claims 9-11, 18-20, 28-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Burstrom & Fennelly as applied to claims 1 above, and further in view of Pasternack (DE 26-52-136).

In regards to claims 9-10, 19-20, 28-29, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose storage of results in a database. However, Pasternack disclose such (See disclosure of

element 15 of Pasternack, use/creation of a "data log"). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Pasternack and used them with the suggested device. The suggestion/motivation for doing so would have been to document the results of the test for future use/reference. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 11, 30 the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose monitoring of the test stations during testing. However, Pasternack disclose such. (See disclosure of element 15 of Pasternack, use/creation of a "data log"). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Pasternack and used them with the suggested device. The suggestion/motivation for doing so would have been to document the results of the test for future use/reference. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 18, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose selectively shutting off testing of an individual test subject. However, Pasternack disclose such. (Note the feedback sensor of Pasternack (13) which controls aerosol generator 10). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Pasternack and used them with the suggested device. The suggestion/motivation for doing so would have been to conserve aerosol materials when the device is not testing a test subject. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

3. Claims 12, 31 & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burstroem & Fennelly as applied to claims 1 & 26 above, and further in view of Tilley (US 6435009).

In regards to claim 12, 31 & 39 the suggested device/method substantially discloses the instant application's claimed invention, but does not explicitly disclose the capturing and storage of images. However, Tilley disclose such (See Tilley disclosing the monitoring of screens 272-282 & 370-380 and 398 and the data depicted on the screen being "captured" in memory, the data log). The references are analogous since they are from the same field of endeavor, the testing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Tilley and used them with the suggested device/method. The suggestion/motivation for doing so would have been to document the mask fit data for medical records/exposure/documentation purposes. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burstroem & Fennelly as applied to claim 22 above, and further in view of Loedding et al. (US 5156776).

The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a nebulizer as the aerosol generator. However, Loedding disclose such (See element 2). The references are

analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Loedding and used them with the suggested device. The suggestion/motivation for doing so would have been to because use of a nebulizer falls within the scope of an aerosol generator and because use of a nebulizer produces an optimal and uniform aerosol cloud. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

5. Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

However, please not that Paternack & Fennelly are not being used for "quantitative" mask test fit subject matter. Furthermore applicant's use of the adjective or label "qualitiative" instead of "quantitiative" in no way, shape or form alters the substantive nature of the same elements being manipulated as viewed by one of ordinary skill in the art. Thus it cannot be invoke the use of this non-distinguishing adjective as a talisman to serve as a patentable distinction. I.e. applicant is merely pointing out a semantic difference that does not amount to an actual difference, let alone one that can serve as evidence of a patently distinct inventive step over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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3/25/04

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